REMARKS

I. Rejections Under 35 USC § 112

Claims 1-24 were rejected as failing to comply with the enablement requirement because the examiner is unable to identify "pre-detection criteria" in the written description. Attention is invited to paragraph [50] wherein sudden onset criteria and rate stability are identified as parameters along with ventricular interval rate that are evaluated before VF or VT detection is made. While persons of skill in the art would recognize these parameters as "pre-detection criteria," the claims have been amended to include a recitation of "having an algorithm for detection of a spontaneous tachyarrhythmia episode from detected cardiac signals in accordance with detection criteria that includes an onset of detection criteria." The rejection of the claims for lack of enablement is obviated.

Claims 1-24 were also rejected as being indefinite. The variously identified recitations cited in reliance of the rejection have been amended to remove the alleged indefiniteness. The rejection of the claims as being indefinite is obviated.

II. Rejections Under 35 USC § 103

Claims 1-24 were rejected under 35 USC § 103(a) as being obvious over Nau et al. (US 5,732,708) in view of Paul et al. (US 5,944,744).

Pending claims 1-7 are directed to a method, and pending claims 13-18 are directed to apparatus.

Nau relates to an ICD capable of storing digitized EGM data in an EGM memory block 24. But, in Nau, if an arrhythmia episode is detected, but normal rhythm returns prior to therapy delivery, the EGM data is discarded and not permanently stored (col. 9, lines 52-61). Only if therapy is delivered is the EGM data corresponding to the episode permanently stored and thus available for subsequent diagnostic use (col. 9, line 65 to col. 10, line1).

The office action finds that the differences between Nau and the claimed subject matter are only (1) that a sense amplifier is absent[1], and (2) while allegedly measuring peak amplitude, use of the peak amplitude measurements to adjust sensing threshold is absent. Thus, Paul is relied upon as allegedly showing a sense amplifier and adjusting sensing thresholds based upon stored peak amplitudes of the cardiac signals. The contention is that the combination of Nau and Paul results in the claimed subject matter.

The claimed subject matter specifies that measurement of detected peak amplitudes of the sensed cardiac signals begins at an onset of detection of a spontaneous tachyarrhythmia episode and continue until normal rhythm returns (i.e., whether by therapy delivery termination or by spontaneous termination without therapy delivery). The data representing the detected peak amplitude measurements is stored and used in adjusting sense amplifier sensing threshold.

The obviousness rejection fails, at a minimum, because the differences between the scope and content of Nau and the claimed subject matter are much greater than expressed in the office action. Most importantly, Nau does not measure detected peak amplitudes of the analog EGM signal. Despite storing a digitized EGM, Nau does not disclose the measurement of *detected* EGM peak amplitudes. The office action's characterization of Nau as inherently measuring peak amplitude merely because the recorded EGM represents a measured cardiac signal is misplaced. Nau simply samples and digitizes the entire analog EGM waveform. Nau does not measure detected peaks of the EGM waveform and store them. Nowhere does Nau even consider detecting peak amplitudes of the EGM signal and storing data representing measurements of those detected peak amplitudes.

[1] This finding is made even though Nau's disclosure is in the context of an ICD, which would necessarily include a sense amplifier.

Paul discloses an IPG with a programmable sense amplifier and provides automatic sensitivity control. As the peak amplitude 136 of the EGM 130 changes, the change is tracked by adjustment of outer and inner target reference voltages 132,134, which are used to adjust sensitivity thresholds so that peaks of the EGM are between the outer and inner targets. The operation is illustrated in Fig. 4:

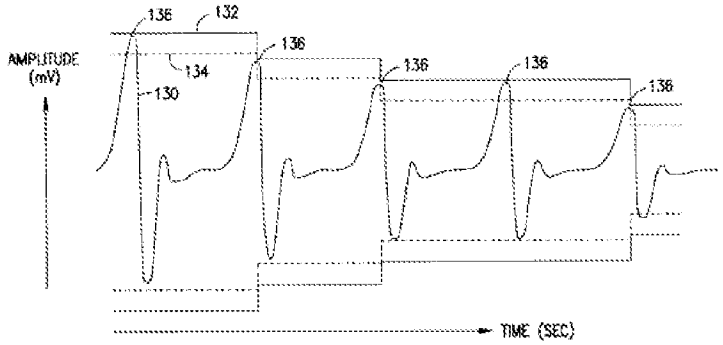

FIG. 4

The disclosed circuitry to implement the operation of Fig. 4 is shown in Fig. 3:

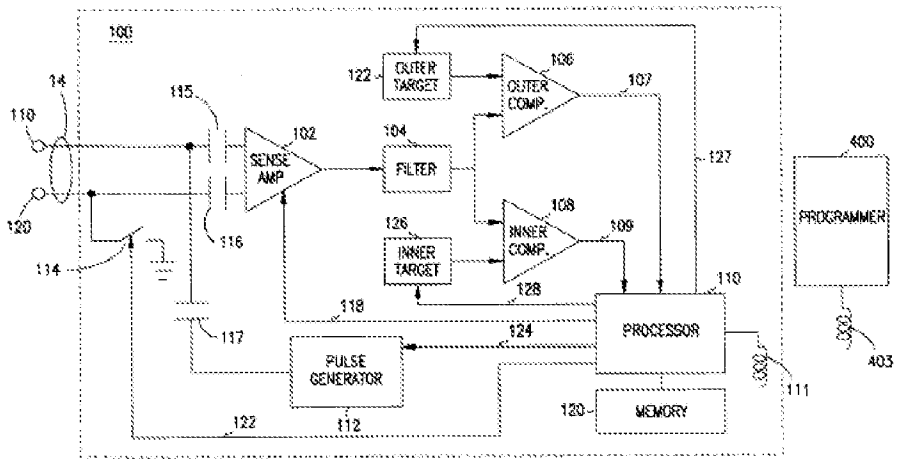

FIG. 3

In Paul, the signal peaks are not detected, measured, and stored. Only a digital representation of the magnitude of the outer target reference 132 is stored. See Paul, col. 8, lines 46-62. Moreover, the cardiac signals are not indicated to

be ones that occur during a spontaneous tachyarrhythmia episode. In fact, the disclosure is in the context of a device performing a pacing function. See, col. 5, line 34-36 ("The implantable medical device 100 may include a pacemaker or any medical device that performs pacing functions, including many defibrillators."); col. 6, lines 23-25 ("Referring now to Fig. 3, the components of pacer 100 particularly relevant to the invention generally include…"). In that context, the cardiac signals shown in Fig. 4 can not be of a spontaneous tachyarrhythmia episode. Yet further, the indication is that Paul teaches that the automatic sensitivity adjustment, which results in the stored value of the outer target reference, is conducted on a continuous basis, whereas the claims specify that measurement of detected peak amplitudes of the sensed cardiac signals is only conducted at the beginning of an onset of detection of a spontaneous tachyarrhythmia episode and ends when normal rhythm returns.

Combining Nau and Paul results in an ICD wherein the sensitivity threshold of a sense amplifier that detects cardiac signals for arrhythmia detection is continuously, during both normal cardiac rhythm and an arrhythmia episode, adjusted based upon an approximation of the changing peak amplitude of the cardiac signals. Both Nau and Paul fail to provide the limitation that a measurement of detected peak amplitudes of the sensed cardiac signals begins at an onset of detection of a spontaneous tachyarrhythmia episode and continues until normal rhythm returns.

Further, although the office action characterizes Paul as disclosing use of an external device to adjust sensing threshold based on telemetry of stored cardiac signal peak data, Paul in fact does not adjust sensing threshold. Paul teaches that a physician can use the information to place limits on the pacer's automatic sensitivity control capability (col. 8, line 66 to col. 9, line1).

The clear conclusion is that the office action is incorrect. The result of combining Nau and Paul does not result in the claimed subject matter as a whole. Accordingly, the rejection of the pending claims fails and should be withdrawn.

Furthermore, there is no motivation to combine Paul with Nau. Whereas Paul continuously adjusts the sensitivity of the sense amplifier, which in turn requires continuous tracking of the cardiac signal peaks, Nau only records digitized EGM data if an arrhythmia event is detected and therapy is delivered. Also, Paul does not provide for recording a breadth of EGM data, including EGM waveform morphology, for a diagnostic purpose that is the central focus of Nau. As stated in Paul, "only a close approximation of the electrogram" is provided (col. 8, lines 64-65). Accordingly, the rejection of pending claims fails for this reason also and should be withdrawn.

III. Conclusion

There being no further outstanding objections or rejections, it is submitted that the application and all pending claims are in condition for allowance. An early action to that effect is courteously solicited.

Finally, if there are any formal matters remaining after this Amendment, the Examiner is requested to telephone the undersigned attorney to attend to those matters.

Respectfully submitted,

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Date

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